



Application No. 10/045,730
Attorney Docket No. 10071-018-999

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
TECH CENTER 1600/2900

Application of: Mason

Application No.: 10/045,730

Group Art Unit: 1615

Filed: October 19, 2001

Examiner: Isis A.D. Ghali

For: STERILE, BREATHABLE PATCH FOR
TREATING WOUND PAIN

Attorney Docket No.: 10071-018-999

RESPONSE TO RESTRICTION REQUIREMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

In response to the Office Action mailed March 26, 2003, in which the captioned application was examined for restriction purposes only. Applicant respectfully requests entry of the following remarks and provisional elections into the file of the application.

REMARKS

On pages 2-3 of the Office Action, the Examiner has sought to restrict the application to one of the following two alleged inventions: Group I, claims 1-43, drawn to a patch and a package containing a patch comprising a breathable backing coated with polyvinylpyrrolidone-based hydrogel that comprises a local anesthetic, and methods of using the same; and Group II, claims 44-53, drawn to a polyvinylpyrrolidone-based hydrogel that comprises a local anesthetic.

Applicant respectfully traverses the restriction requirement and requests either withdrawal or modification thereof in accordance with the discussion below. In order to be fully responsive, Applicant provisionally elects, with traverse, Group I, claims 1-43 for immediate prosecution on the merits. Applicant expressly reserves the right to file one or more divisional or other continuing applications to protect the inventions of the non-elected

claims and other disclosed, but unclaimed, subject matter prior to the issuance of this application.

Applicant respectfully submits that the claims in Group I & II are all directed to a polyvinylpyrrolidone-based hydrogel that comprises a local anesthetic. Thus, this specific feature is present in all the claims. Therefore, even if Applicant was to elect one of the groups, the required search would necessarily encompass the subject matter of the other group.

As stated in § 803 of the *Manual of Patent Examining Procedures* (August, 2001) (“MPEP”):

If the search and examination of an entire application can be made without **serious burden**, the examiner **must** examine it on the merits, even though it includes claims to distinct or independent inventions (emphasis added).

Thus, all of the subject matter in Groups I & II should be examined together. Moreover, even if the subject matter of these groups were distinct inventions, it would not be a “serious burden” on the Examiner to search these groups in this application. Applicant, therefore, respectfully requests that the restriction of the claims be reconsidered and withdrawn.

On pages 3-5 of the Office Action, the Examiner also asserts that the pending claims are directed to more than one species of the generic invention. Specifically, it is alleged that, within Group I: (a) method of inducing local anesthesia, claim 22, and (b) method of treating pain associated with a non-intact skin, claim 33; and within Group I or II, as local anesthetics: (a) sodium channel blocker, (b) antidepressant, (c) NMDA receptor antagonist, and (d) opioid.

Before addressing the Examiner’s requirement regarding election of species, Applicant respectfully submits that the Examiner’s characterization of the claimed invention is incorrect. The Examiner seems to imply that methods of inducing local anesthesia, as recited in claims 22-32, are mutually exclusive with methods of treating pain associated with a non-intact skin, as recited in claims 33-43. Applicant respectfully submits that this characterization of the claimed invention is incorrect. Nothing in any of the claims or the specification suggests that a method of inducing local anesthesia could not, at the same time,

treat pain associated with a non-intact skin. In fact, it is entirely possible that a method of applying a breathable patch of the present invention comprises both inducing local anesthesia treating pain associated with a non-intact skin. Therefore, Applicant submits that the Examiner's characterization of the invention is incorrect, since methods of inducing local anesthesia, as recited in claims 22-32, are not mutually exclusive with methods of treating pain associated with a non-intact skin, as recited in claims 33-43.

The Examiner also seems to imply that patches, packages and methods of use that comprise one of the local anesthetics, *e.g.*, recited in claim 5, are mutually exclusive with those that comprise other local anesthetics recited in claim 5. Applicant respectfully submits that this characterization of the claimed invention is also incorrect. Nothing in any of the claims or the specification suggests that a patch, package or method of use that comprises one of the local anesthetics could not, at the same time, comprise other local anesthetics. In fact, it is entirely possible that a patch could comprise more than one local anesthetics, *e.g.*, as recited in claims 1 and 5. Therefore, Applicant submits that the Examiner's characterization of the invention is incorrect, since a patch, package or method of use that comprises one of the local anesthetics, are not mutually exclusive with those that comprise another of the local anesthetics.

As the Examiner is well aware, "[c]laims to be restricted to different species **must be mutually exclusive**." *MPEP* § 806.04(f) (emphasis added). "The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first." *Id.*

As discussed above, methods of inducing local anesthesia are not mutually exclusive with methods of treating pain associated with a non-intact skin; and a patch, package or method of use that comprises one of the local anesthetics, are not mutually exclusive with those that comprise another of the local anesthetics. For this reason alone, the required election of species should be withdrawn. *Id.* Furthermore, the patches, packages and methods recited in claims 1-43, while maybe comprising different elements, all recite the features of a patch comprising a breathable backing coated with polyvinylpyrrolidone-based hydrogel that comprises a local anesthetic. There is no suggestion that any of the claims does not require those features. Thus, a search to that effect would encompass all the alleged

species. Applicants therefore submit that the restriction of species, at least within claims 1-43, is inappropriate and should be withdrawn. *Id.*

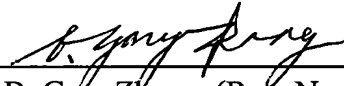
In order to be fully responsive, Applicant elects, with traverse, method of inducing local anesthesia as the method and sodium channel blocker as the local anesthetic for prosecution on the merits. Applicants expressly reserve the right to file one or more divisional or other continuing applications to protect the inventions of the non-elected species and other disclosed, but unclaimed, subject matter prior to the issuance of this application.

In conclusion, Applicant respectfully submits that the restriction and election of species requirements set forth in the Office Action are inappropriate and should be withdrawn. Applicant further respectfully submits that, at a minimum, the species requirement within the elected claims 1-43 should be reconsidered and withdrawn.

No fee is believed due for this submission. Should any fees be required, however, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date 4/25/2003


B. Gary Zhang (Reg. No. 47,331)

PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, DC 20006
(202) 496-4400

For: Samuel B. Abrams (Reg. No.: 30,605)
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, NY 10036-2711
(212) 790-9090